

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

This document relates to:

*The County of Cuyahoga v. Purdue
Pharma L.P., et al.*, Case No. 17-OP-45004

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P. et al.,
Case No. 18-OP-45090*

**MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION TO EXCLUDE THE OPINIONS AND
TESTIMONY OF CRAIG MCCANN**

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INTRODUCTION

Defendants move to exclude the report, supplemental reports, exhibits, and testimony of Dr. Craig McCann. McCann is a data expert Plaintiffs retained to “summarize shipments in the ARCOS Data” into Cuyahoga and Summit County, and to “report the results of applying certain algorithms to the ARCOS Data.”¹ Those algorithms—aided substantially by an assumption directed by counsel—led McCann to identify or “flag” between 75% and 87% of all opioid shipments to the Track One counties, or more than 90% of all pills. In other words, McCann’s math is the basis for Plaintiffs’ staggering claim that only 10% of the prescription opioids sold to patients in the Track One counties over the past 23 years were lawfully distributed.

McCann ran certain of his algorithms incorrectly and has no experience in suspicious order monitoring, but those are not even the core flaws in his analysis. The central flaw is that his analysis has no connection to what Plaintiffs contend is “the pertinent inquiry” of this case as it relates to alleged “suspicious orders.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591–92 (1993). Plaintiffs contend Defendants shipped, or failed to monitor, suspicious orders of prescription opioids in violation of a legal duty,² and the orders flagged by McCann are being offered as those that should not have been shipped.³ But the algorithms he used to identify those orders do not purport to reflect any legal duty actually owed by Defendants; they merely are alternative methods that Defendants *could have* but were *not required* to use, and neither he nor Plaintiffs’ DEA expert offers any opinion that failure to use those particular methods amounts to the breach of a legal duty. Nor could they. The undisputed record is that DEA refuses to endorse

¹ Ex. 1, Expert Report of Craig McCann at 4.

² While not the subject of this motion, Defendants dispute plaintiffs’ characterization of this legal duty as stated in their June 24, 2019 motion for partial summary judgment. *See* ECF No. 1732.

³ Ex. 2, Expert Report of James Rafalski, at 40–46.

specific methods or algorithms for identifying suspicious orders and instead requires registrants to design their own systems, tailored to their own customers and business models.

Plaintiffs cannot prove negligence without proving Defendants acted unreasonably. The orders “flagged” by McCann would be wholly irrelevant except as a measure of the “suspicious orders” shipped by Defendants in violation of some legal duty. Because they are nothing of the kind, McCann’s analysis does not fit the facts of this case and should be excluded. *See Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (requiring a “connection between the … test result being offered and the disputed factual issues in the case”). McCann’s analysis also suffers from additional flaws, described below, that present independent grounds for exclusion.

BACKGROUND

Under the Controlled Substances Act (“CSA”), registrants are required to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and to inform the DEA “of suspicious orders when discovered.” 21 C.F.R. § 1301.74(b). Plaintiffs claim, relying on McCann, that Defendants violated legal duties by (1) shipping suspicious orders (Distributors), and (2) failing to monitor those downstream transactions (Manufacturers).

A. McCann’s Analysis

McCann’s report describes “a non-exhaustive set of [five] algorithms” for identifying suspicious orders that he applied to ARCOS and Distributor transaction data, resulting in five alternative opinions regarding the number of orders that should not have been shipped, including an identification of the manufacturer of the shipped opioid product.⁴ McCann did not develop these algorithms; they were provided to him by counsel for Plaintiffs, who received them from

⁴ Ex. 1, McCann Rpt, at 6; Ex. 3, McCann Second Supplemental Report., at 2. Plaintiffs also asked McCann to offer certain opinions relating to the reliability of ARCOS and Defendant transaction data, which are not addressed in this motion.

their DEA expert James Rafalski.⁵ McCann referred to himself as “a calculator” and “a computer” who simply “took these approaches and implemented them.”⁶ He is not an expert in suspicious order monitoring, offers no opinions about whether his algorithms are appropriate or required, and agrees that there could be other appropriate methods to identify suspicious orders.⁷

Rafalski himself acknowledged that four out of the five algorithms that McCann applied are not appropriate methods for identifying suspicious orders, and thus they cannot reflect legal duties owed by Defendants.⁸ Further, Rafalski characterized what, in his view, is the only acceptable of McCann’s algorithms —the Six-Month Trailing Threshold (“SMTT”)—as merely a “potentially suitable” method for identifying suspicious orders.⁹ Under this method, an order is identified if it causes the total monthly purchases by a pharmacy to exceed the highest monthly total from any one of the prior six calendar months.¹⁰ But while Rafalski considers SMTT to be one “potentially suitable” method that Defendants could have used, he offers no opinion that any Defendant was *required* to use that method, and acknowledged that there may be other suitable methods for identifying suspicious orders.¹¹ The SMTT algorithm is based on a system peculiar to one other registrant, (non-defendant) Masters Pharmaceutical, Inc., which was the subject of an enforcement action and subsequent appeal to the U.S. Court of Appeals for the D.C. Circuit. No

⁵ Ex. 4, Deposition of Craig McCann (“McCann Tr.”) 134:13–17; *see* Ex. 5, Deposition of James Rafalski (“Rafalski Tr.”) 163:4–13.

⁶ Ex. 4, McCann Tr. 129:6–15; 135:14–24.

⁷ Ex. 4, McCann Tr. 108:2–109:4; 129:6–15; 269:1–270:9.

⁸ Ex. 5, Rafalski Tr. 174:5–10; 356:19–357:2 (stating that the other four methodologies, in his view, “aren’t suitable suspicious order systems”).

⁹ Ex. 5, Rafalski Tr. 480:17–481:20.

¹⁰ Ex. 1, McCann Rpt, at 56.

¹¹ Ex. 5, Rafalski Tr. 483:21–484:8.

other registrant would have been aware of the SMTT system used by Masters until the proceedings of the enforcement action were made public in 2014. And DEA has never indicated that any other distributor should have used the SMTT method, or any other particular method, stressing—as discussed below—registrants’ *obligation* to design their own suspicious order monitoring programs based on considerations unique to them.

Of greatest significance to McCann’s math, he was asked by counsel to assume that once a pharmacy order triggers one of his algorithms, *every subsequent transaction* to that pharmacy for that particular drug—no matter how small or how remote in time from that first flagged order—automatically should be flagged too, like knocking over dominoes.¹² Not surprisingly, this assumption dramatically increases the number of flagged orders. McCann made no effort to determine which, if any, of the automatically-flagged orders would have been triggered by independent operation of the algorithms, i.e. without the assumption directed by counsel.¹³ He did acknowledge that without the assumption (and automatic rule), “you don’t flag very many orders.”¹⁴ For example, under the SMTT algorithm-plus-assumption, McCann flags 92.9% of all transactions by Cardinal Health. Only 5.3% would have been triggered by operation of the algorithm alone.¹⁵ The practical implication is that McCann’s algorithms do not drive the conclusion that 90% of pills should not have been shipped; this assumption does.¹⁶

¹² Ex. 1, McCann Rpt., at 56–57; Ex. 4, McCann Tr. 366:21–367:13. The ostensible basis for this assumption is that Defendants conducted no “due diligence” of orders that were flagged. The validity and reliability of the assumption is addressed in the *Daubert* motion relating to Rafalski.

¹³ Ex. 4, McCann Tr. 145:8–146:15.

¹⁴ Ex. 4, McCann Tr. 294:24–295:7.

¹⁵ Ex. 6, Expert Report of John MacDonald III, at 34.

¹⁶ Notably, McCann does not evaluate any orders actually shipped directly by Manufacturers. Instead, his analysis with respect to Manufacturers focuses solely on purchases by pharmacies in Cuyahoga and Summit County from distributors of manufacturers’ product based on counsel-directed assumptions that “manufacturers could have developed intelligence on shipments of its

B. DEA Documents and Testimony Relating to Suspicious Order Monitoring

The DEA is the agency responsible for administering the CSA, including the regulations relating to suspicious order monitoring. It has never endorsed algorithms like McCann's as the standard for compliance with the CSA. According to the uniform testimony of DEA witnesses in this litigation, (1) the DEA does not approve or endorse one specific methodology for identifying suspicious orders; (2) there is more than one way to design a compliant system; (3) the criteria that identify a suspicious order will vary across registrants, customers, and situations; and (4) a registrant may ship orders it has determined not to be suspicious even though that same customer previously placed an order that is undergoing review.

1. In a December 2007 guidance letter, the DEA informed registrants that “[t]he regulation clearly indicates that it is the sole responsibility of the registrant to design and operate” a suspicious order monitoring system, and therefore “DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.”¹⁷ DEA witnesses in this case corroborated this position, including DEA’s 30(b)(6) representative on this subject, who testified that DEA has never instructed registrants to set a monthly threshold at a specific level.¹⁸

2. DEA witnesses uniformly acknowledged that there is more than one way to design and operate a system that can identify and report suspicious orders, and that the DEA expects that each registrant will design a system that is tailored to its business model and customer base.¹⁹ As

drugs to Dispensers in Cuyahoga County and Summit County” and “did not effectively investigate the flagged transactions.” Ex. 3, McCann Second Supplemental Rpt., at 20.

¹⁷ Ex. 7, Letter from Joseph Rannazzisi, December 27, 2007, US-DEA-00017912, at 1.

¹⁸ Ex. 8, Deposition of Thomas Prevoznik (“Prevoznik Tr.”) 263:9–17; *see also* Ex. 9, Deposition of Joseph Rannazzisi (“Rannazzisi Tr.”) 338:4–12; Ex. 10, Deposition of Kyle Wright (“Wright Tr.”) 345:19–25.

¹⁹ Ex. 8, Prevoznik Tr. 179:22–180:6; 1177:15–19; 1191:21–1192:7; *see also* Ex. 9, Rannazzisi Tr. 315:24–316:12; Ex. 11, Deposition of Demetra Ashley (“Ashley Tr.”) 88:2–10.

Joseph Rannazzisi, former head of the Office of Diversion Control, testified, “How they create that system is a business decision and as long as it identifies and reports suspicious orders, . . . and they are comfortable with that system, they have a system.”²⁰

3. According to the DEA, “the variables that indicate an order is suspicious are ***very fact intensive and differ from distributor to distributor, and from customer to customer.***”²¹ DEA witnesses uniformly corroborated this position, including DEA’s 30(b)(6) witness who testified that “what is appropriate for one pharmacy may be completely different than the requirements of another pharmacy,” and therefore, the determination of whether an order is suspicious is “based on a number of different factors” that “only a distributor can know.”²²

4. A registrant may ship orders they have determined not to be suspicious even though that same customer previously placed an order that is undergoing review. DEA 30(b)(6) representative Thomas Prevoznik was asked about a hypothetical situation in which a distributor is investigating a potentially suspicious order, and in the meantime, receives additional orders from that same pharmacy that do not look suspicious to the distributor. He confirmed that it is “okay for the distributor in that instance to exercise their business judgment and send those nonsuspicious orders out.”²³

²⁰ Ex. 9, Rannazzisi Tr. 321:8–21.

²¹ Ex. 12, *Prescription Drugs: More DEA Information about Registrants’ Controlled Substances Role Could Improve Their Understanding and Ensure Access*, GAO-15-471 (June 2015), at 81.

²² Ex. 13, Deposition of Matthew Strait (“Strait Tr.”) 40:3–14; *see also* Ex. 9, Rannazzisi Tr., at 274:10–275:3; 282:4–17; 538:20–540:11; 549:22–550:23; Ex. 10, Wright Tr. 106:6–15; Ex. 11, Ashley Tr., at 26:9–27:13; 246:4–22.

²³ Ex. 8, Prevoznik Tr. at 1236:24–1238:20.

ARGUMENT

I. McCann’s Algorithms Do Not Identify Suspicious Orders that Defendants were Required to Report, So His Analysis of “Flagged” Transactions Does Not “Fit” an Issue in this Litigation.

As relevant here, under Plaintiffs’ theory, the pertinent inquiry is whether Defendants shipped or failed to monitor orders of prescription opioids in violation of a legal duty, such as a duty based on the requirement to identify “suspicious orders” under 21 C.F.R. § 1301.74(b). McCann’s flagged transactions are offered as a measure of the “suspicious orders,”²⁴ but they do not inform that issue, and thus do not fit the facts or legal theories of the case.

A. None of the Methodologies Reflects Defendants’ Legal Duties.

Neither McCann nor Rafalski, on whom he relies, opines that Defendants had a legal obligation or duty to use any of McCann’s flagging methodologies to identify suspicious orders. McCann readily conceded that he is not an expert in suspicious order monitoring, and that he was not “vouching in any way” for the assumptions he was asked to make.²⁵ He conducted no analysis of whether his methods flagged a realistic number of transactions,²⁶ and testified that he does not have any opinion on whether “a flagged transaction is necessarily a suspicious order,” or whether his “non-exhaustive” algorithms are appropriate or legally required by the CSA.²⁷ Such questions are, according to him, “way beyond my report.”²⁸

Likewise, Rafalski does not offer any opinion that McCann’s flagging methodologies encompass Defendants’ legal duties. To the contrary, Rafalski:

²⁴ Ex. 2, Rafalski Rpt. at 41.

²⁵ Ex. 4, McCann Tr. 109:2–4; 375:19–376:10.

²⁶ Ex. 4, McCann Tr. 487:4–12.

²⁷ Ex. 4, McCann Tr. 149:17–23; 283:11–284:22.

²⁸ Ex. 4, McCann Tr. 149:3–8.

- Declined to endorse any of the methodologies, including SMTT, citing DEA's policy not to endorse suspicious order monitoring systems;²⁹
- Disavowed four of the five algorithms as not reasonable, and stated only that the SMTT method was "potentially suitable" under the CSA³⁰ and "provides a reasonable estimate and an initial *first step* to identifying orders of unusual size";³¹
- Offered no opinion that a registrant who did not use the SMTT method was acting unreasonably, or that the orders flagged under the SMTT are orders that necessarily satisfy the definition of suspicious order;
- Admitted there may be other methods that registrants use that would be sufficient and that "reasonable minds can disagree as to whether or not an order is suspicious";³²
- Admitted that, as part of his expert assignment, "there wasn't a requirement for me to actually find specific orders that were suspicious";³³
- Declined to actually "identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully," stating it would be "an impossible task."³⁴

Identifying orders that Defendants would have detected using a "potentially suitable" or "reasonable" system falls far short of identifying orders that Defendants were duty-bound to detect. Plaintiffs' burden is to prove that individual Defendants acted ***unreasonably***, not that other conduct would have been reasonable. An opinion identifying the orders that would have been flagged for review under one "reasonable" method is not an opinion that shipping those orders was unreasonable or unlawful. Neither McCann, nor Rafalski, nor any other expert witness offers an opinion of the orders they actually claim were suspicious and shipped in violation of applicable legal duties. The fact that the Defendants did not identify as "suspicious" the same orders that McCann "flagged" says nothing at all about which orders Defendants should not have shipped.

²⁹ Ex. 5, Rafalski Tr. 503:5–15.

³⁰ Ex. 5, Rafalski Tr. 481:3–19.

³¹ Ex. 2, Rafalski Rpt, at 46.

³² Ex. 5, Rafalski Tr. 404:23–405:2; 483:21–484:8.

³³ Ex. 5, Rafalski Tr. 192:10–21.

³⁴ Ex. 2, Rafalski Rpt, at 46.

The Fourth Circuit's decision in *Sexton By and Through Sexton v. Bell Helmets, Inc.*, 926 F.2d 331 (4th Cir. 1991), is instructive. There, plaintiff's expert sought to opine that defendant's design of a motorcycle helmet was defective because she conceived of other designs with greater safety features. *Id.* at 337. In rejecting that testimony, the court explained:

[T]he record in the case before us reveals no government or industry standard that would have required Bell to incorporate Dr. Saczalski's prototype design into its helmets. ... No literature was presented to indicate that anyone—industry, government, or consumers—recognized a need for greater protection in low impact accidents than that provided for by these standards. ... *Dr. Saczalski testified to that which could have been done to avoid plaintiff's injuries in this case. But that is not the equivalent of what was required to have been done...*

That an alternative design was “feasible” is at best hindsight. Looking back on the progressions of technology, it is easy to fall into a mind-set of imposing current knowledge and expectations on older standards or expectations. But we cannot, under the law, judge yesterday's design by contemporary standards or expectations

Id. at 337-38 (vacating judgment and remanding for new trial based upon improper admission of expert testimony); *see also Belville v. Ford Motor Co.*, 919 F.3d 224, 236 (4th Cir. 2019) (“[T]he availability of an alternative vehicle design with [a particular safety system] does not substantiate the Plaintiffs' theory of defect because the alternative design's mere availability does not prove that the existing design is defective or could lead to a [negligent act].”).

For the same reasons, McCann's identification of orders that Defendants would have reviewed had they followed a method they were under no legal obligation to follow is not actually a measure of the orders Defendants were obligated to review. And if McCann's flagged transactions do not reflect orders shipped in violation of a legal duty actually owed by Defendants, his opinions cannot help the jury determine whether Defendants acted negligently, and thus do not “fit” the issues in the case and should be excluded. *See also Pride*, 218 F.3d at 578 (requiring a

“connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify”); *Meadows v. Anchor Longwall and Rebuild, Inc.*, 306 Fed. Appx. 781, 791 (3d Cir. 2009) (Unpublished) (holding expert testimony which “lacked a factual foundation in the record to satisfy the fit requirement … was properly excluded”); *Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) (expert’s testimony premised on a factual circumstance nowhere in evidence did not fit and was properly excluded).

B. DEA Documents and Testimony Foreclose an Opinion that McCann’s “Flagged Transactions” are Suspicious Orders.

Not only do McCann and Rafalski fail to offer any opinion that Defendants’ breached a legal duty by not using McCann’s algorithms, nothing in the record could support holding McCann’s flagged transactions out as the measure of Defendants’ alleged breach.

As an initial matter, DEA has never endorsed McCann’s methods as the standard for compliance with the CSA. Since 2007, the DEA repeatedly has informed registrants that it will not endorse specific suspicious order monitoring systems.³⁵ While the DEA has “long understood” that registrants wanted a “DEA-established threshold,”³⁶ the DEA has never instructed registrants to set monthly thresholds at a specific level,³⁷ nor identified “a particular formula or algorithm that is required for a legally compliant system.”³⁸

Moreover, Distributors’ shipment decisions cannot be judged against McCann’s one-size-fits-all methods because “the variables that indicate an order is suspicious ***are very fact intensive***

³⁵ Ex. 7, at 1; Ex. 9, Rannazzisi Tr. 338:4–12; Ex. 10, Wright Tr. 345:19–25.

³⁶ Ex. 13, Strait Tr. 40:15–22.

³⁷ Ex. 8, Prevoznik Tr. 179:22–180:6; 194:8–195:9.

³⁸ Ex. 11, Ashley Tr. 88:2–10.

and differ from distributor to distributor, and from customer to customer.”³⁹ According to the DEA, “pharmacies that are around the corner from one another may have vastly different profiles that are acceptable,” and the DEA “feels very strongly” that these are circumstances “that only a distributor can know.”⁴⁰ Thus, how a distributor designs its own system is “a business decision based on what the registrant’s needs are.”⁴¹ A distributor could decide, like Masters Pharmaceutical, that the SMTT method is an appropriate fit for its customers and business model. But another distributor might choose to consider different variables that the SMTT method ignores, like a customer’s geographic location, proximity to hospitals, ordering patterns of nearby pharmacies, percentage of controlled to noncontrolled substances, etc.—all of which could be appropriate considerations according to the DEA.⁴² A distributor that uses different variables inevitably would identify some orders as potentially suspicious that McCann would not identify, and vice versa. Any daylight between the orders McCann would identify and those that distributor would identify could only reflect negligent conduct if somehow there was an obligation to follow McCann’s methods. The uniform testimony of DEA witnesses makes clear that is not the case. There is, thus, no basis to hold McCann’s opinions out as a measure of Defendants’ alleged breach.

C. McCann’s Approach—Aided By His Counsel-Directed Assumption—is Unfounded and Prejudicial.

Suggesting that Defendants are liable for not using a method they had no duty to use is prejudicial, and all the more so because of McCann’s counsel-directed assumption to treat all orders after the “first flagged orders” as likewise being suspicious. As noted above, that

³⁹ Ex. 12, GAO Report at 81.

⁴⁰ Ex. 13, Strait Tr. 40:3–41:16

⁴¹ Ex. 9, Rannazzisi Tr. 315:24–316:12.

⁴² Ex. 8, Prevoznik Tr. 181:18–22; Ex. 9, Rannazzisi Tr. 261:12–19; 274:10–275:9; 315:24–316:12.

assumption is the primary driver of McCann’s calculation, causing an algorithm that otherwise would flag ~5% of orders as suspicious to instead flag upwards of 90%. Because Defendants did not and were not required to use the SMTT criteria, the Defendants did **not** have an “unfulfilled obligation to detect and investigate the first [McCann] flagged transaction” (as opposed to their own flagged transactions).⁴³ But under McCann’s analysis, his first flagged transaction is the domino that knocks down all the others. Thus, even though a transaction that triggers McCann’s algorithms probably is not one that any Defendant would have identified as requiring further diligence, Defendants are penalized for applying, at DEA’s insistence, their own criteria.

Indeed, McCann admits that he did **not** even “consider any documents relating to investigations that defendants may have done into potentially suspicious orders[.]”⁴⁴ He therefore does not and cannot know whether Defendants in fact investigated the same transaction he first flagged, or whether they investigated subsequent transactions from the same customers. McCann’s calculations are impermissibly the product of bare assumptions on an issue he failed to investigate. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 140–41 (1997) (“Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”)

* * *

Using McCann’s analysis, Plaintiffs claim that nearly all of the prescription opioid orders shipped by Defendants violated a legal duty. But McCann’s identification of “flagged transactions” is meaningless without a connection between those transactions and the duties that Defendants allegedly violated. Such a connection could only exist if McCann’s methods reflected

⁴³ Ex. 1, McCann Rpt., at 56–57.

⁴⁴ Ex. 4, McCann Tr. 94:3-7.

a legal duty actually owed by Defendants, such that failure to follow them was tantamount to breach. But for the reasons explained above, they do not. McCann's analysis is not a measure of breach, but of orders that Defendants might have identified had they used McCann's particular flagging methods, which they were not required to do and in fact did not. Accordingly, McCann has not identified for the court or the jury the suspicious orders that Defendants allegedly shipped to substantiate Plaintiffs' highly prejudicial claim that upwards of 90% of all orders filled by Defendants were unlawful.

II. McCann's Flagging Analyses Will Not Help to Determine Whether Orders Are Suspicious or Whether Any Opioids Were Diverted.

Even were we to assume that Rafalski's methodologies reflect legal duties owed by Defendants, McCann failed to apply those methods in a way that could assist the trier of fact. *Daubert*, 509 U.S. at 591. For three of the five methods, McCann did not apply the method as Rafalski instructed. For *all* methods, McCann presented his results only in the aggregate, preventing any analysis that could help identify real-world diversion.

First, McCann did not apply three of the five methods as Rafalski instructed. Rafalski testified that he provided his five methods to Plaintiffs, and that those methods appeared in Plaintiffs' interrogatory responses.⁴⁵ For two of the methods, Rafalski instructed that a national average was to be used,⁴⁶ but for at least several Defendants, McCann used county averages, which had a significant impact on the number of orders flagged.⁴⁷ One of the other methods, "Common Sense Method Two ('Exceeding Threshold of Initial 6 Months and Assuming No Due

⁴⁵ Ex. 5, Rafalski Tr. 500:18–501:15; *see* Ex. 14, Rafalski Dep. Ex. 20 at 6 (Plaintiffs' Jan. 25, 2019, Interrogatory Responses).

⁴⁶ Ex. 14, Rafalski Dep. Ex. 20 at 6 (method 1, Exceeding Threshold of Two Times the National Average, and method 2, Exceeding Threshold of Three Times the National Average).

⁴⁷ *See, e.g.*, Ex. 15, Jena Report at 33; Ex. 16, Brunner Report at 18.

Diligence’),” appears nowhere in McCann’s report. In its place, McCann uses a “Maximum Daily Dosage Units” method, which does not appear among the five methods that Rafalski provided to plaintiffs.⁴⁸ Accordingly, McCann’s flagged transactions do not reflect suspicious orders according to Rafalski’s actual methods and do not fit any issue in the case.

Second, McCann presented the results of *all* of his flagging analyses *only* in the aggregate.⁴⁹ McCann’s flagging results are presented in charts, distributor by distributor, in Appendix 10 to his report. For example, for each method, he presents a single chart for all flagged transactions of Oxycodone that a distributor shipped to all of its customers in Cuyahoga County.⁵⁰ From these aggregated charts, it is impossible to tell how many flagged orders a distributor shipped to any individual customer, and thus impossible to tell whether those orders actually were suspicious, or ultimately diverted for unlawful use. As Rafalski acknowledged, “you can’t tell anything about any individual pharmacy” from McCann’s aggregated charts, and thus there is no way for the trier of fact to draw conclusions as to whether the flagged transactions subsequently were diverted, or alternatively, whether they were validly dispensed.⁵¹ Because McCann’s aggregated data precludes the identification of potential diversion, McCann’s flagging analyses must be excluded under Rule 702 and *Daubert*.

CONCLUSION

For these reasons, the Court should exclude McCann’s opinions and proposed testimony.

⁴⁸ Ex. 4, McCann Tr. 132:4–134:17; *see* Ex. 1, McCann Rpt. at 72.

⁴⁹ Ex. 5, Rafalski Tr. 514:8–515:9; *see* Ex. 17, McCann Report Appendix 10, at 245.

⁵⁰ Ex. 17, McCann Appendix 10 at 245.

⁵¹ McCann similarly presents the aggregate number of transactions between pharmacies and distributors and then simply attempts to tie it back to each manufacturer’s individual product. Such aggregate data provides no information that will assist the trier of fact, because it is impossible to tie the aggregate data to any order shipped by a manufacturer.

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⁵² Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

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CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2019 2019 a copy of the foregoing **DEFENDANTS'** **MOTION TO EXCLUDE CRAIG MCCANN'S OPINIONS AND PROPOSED TESTIMONY** and accompanying exhibits were served via email pursuant to the Court's order.

By: /s/ Ashley W. Hardin

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